

PUBLIC HEALTH DEPARTMENT[641]

Adopted and Filed

Pursuant to the authority of Iowa Code section 136C.3, the Department of Public Health hereby amends Chapter 41, “Safety Requirements for the Use of Radiation Machines and Certain Uses of Radioactive Materials,” Iowa Administrative Code.

The rules are being amended to allow operators to use handheld X-ray equipment without facilities’ needing to obtain a waiver from the Department. Current rules in Chapter 41 prohibit the use of X-ray equipment that is held by the operator during exposures. Over the past few years, manufacturers have developed X-ray equipment specifically designed to be held by the operator during exposures. Over time, the safety of these devices has been confirmed, and industry interest has increased. The Department has been issuing waivers to facilities to allow for the use of this equipment. These amendments remove restrictive language to allow for the use of handheld devices for intraoral radiography only and place into rule operating requirements specific to the X-ray equipment. The operating requirements are currently required as conditions of the waiver. These amendments were drafted with input from the Iowa Dental Association.

Notice of Intended Action was published in the Iowa Administrative Bulletin as **ARC 2901C** on January 18, 2017.

Seven comments were received from the Iowa Dental Association; all have been considered, and several suggestions have been incorporated as follows. In Item 4, the second bullet in numbered paragraph 41.1(7)“c”(5)“2” was amended to make the operator distance requirements consistent throughout the chapter. Numbered paragraph 41.1(7)“c”(5)“3” in Item 4 was also amended to remove the operator requirement of wearing a protective apron. Paragraph 41.1(7)“i” in Item 6 was amended to define the lead equivalency of the protective apron, add language to clarify digital radiography image receptors, change the word “possible” to “practicable,” and add clarifying language regarding storage of the radiography unit. Throughout the amendments, the word “unit” was changed to “equipment,” which is more accurate terminology to describe the handheld dental radiography machine.

The State Board of Health adopted these amendments on May 10, 2017.

After analysis and review of this rule making, no impact on jobs has been found.

These amendments are intended to implement Iowa Code chapter 136C.

These amendments will become effective July 12, 2017.

The following amendments are adopted.

ITEM 1. Amend subrule **41.1(2)**, definition of “X-ray equipment,” as follows:

“*X-ray equipment*” means an X-ray system, subsystem, or component thereof. Types of X-ray equipment are as follows:

a. “Mobile X-ray equipment” means X-ray equipment mounted on a permanent base with wheels or casters for moving while completely assembled.

b. “Portable X-ray equipment” means X-ray equipment designed to be hand-carried but used with a tripod or other stabilization mechanism so the operator is not holding the equipment during exposure.

c. “Stationary X-ray equipment” means X-ray equipment which is installed in a fixed location.

d. “Handheld X-ray equipment” means X-ray equipment designed by the manufacturer to be handheld by the operator during the exposure. X-ray equipment designed without a backscatter shield is prohibited.

ITEM 2. Amend subparagraph **41.1(3)“a”(9)** as follows:

(9) Procedures and auxiliary equipment designed to minimize patient and personnel exposure commensurate with the needed diagnostic information shall be utilized.

1. The speed of film or screen and film combinations shall be the fastest speed consistent with the diagnostic objective of the examinations. Film cassettes without intensifying screens shall not be

used for any routine diagnostic radiological imaging, with the exception of veterinary radiography and standard film packets for ~~intra-oral~~ intraoral use in dental radiography.

2. The radiation exposure to the patient shall be the minimum exposure required to produce images of good diagnostic quality.

3. Portable or mobile X-ray equipment shall be used only for examinations, excluding intraoral dental imaging, where it is impractical to transfer the patient(s) to a stationary X-ray installation. Handheld mobile X-ray equipment may be used for routine intraoral dental imaging in place of stationary equipment. Handheld X-ray equipment shall be used only for intraoral dental radiography.

4. X-ray systems subject to 41.1(6) shall not be utilized in procedures where the source to human patient distance is less than 30 centimeters.

5. If grids are used between the patient and the image receptor to decrease scatter to the film and improve contrast, the grid shall:

- Be positioned properly, i.e., tube side facing the correct direction, and the grid centered to the central ray;
- If the grid is of the focused type, be at the proper focal distance for the SIDs being used.

ITEM 3. Amend subrule 41.1(7), introductory paragraph, as follows:

41.1(7) Intraoral dental radiographic systems. In addition to the provisions of 41.1(3) and 41.1(4), the requirements of 41.1(7) apply to X-ray equipment and associated facilities used for dental radiography. Requirements for extraoral dental radiographic systems are covered in 41.1(6). Only systems meeting the requirements of 41.1(7) shall be used. Additional requirements specific to handheld dental X-ray equipment are outlined in 41.1(7)“i.”

ITEM 4. Amend subparagraph **41.1(7)“c”(5)** as follows:

(5) Each X-ray exposure switch shall be located in such a way as to meet the following requirements:

1. Stationary X-ray systems shall be required to have the X-ray exposure switch located in a protected area or have an exposure switch cord of sufficient length to permit the operator to activate the ~~unit~~ equipment while in a protected area, e.g., corridor outside the operatory. The procedures required under 41.1(3) “a”(4) must instruct the operator to remain in the protected area during the entire exposure.

2. Mobile and portable X-ray systems which are:

- Used for greater than one week in the same location, i.e., a room or suite, shall meet the requirements of 41.1(7) “c”(5)“1.”
- Used for greater than one hour and less than one week at the same location, i.e., a room or suite, shall meet the requirements of the above paragraph or be provided with a 6.5 foot (1.98 m) high protective barrier or means to allow the operator to be at least 9 6 feet (~~2.7~~ 1.8 meters) from the tube housing assembly while making exposure.

3. ~~Portable or hand-held~~ dental X-ray systems designed with a backscatter shield may be used without ~~the an~~ additional protective barrier, but ~~the operator must wear a protective apron.~~ The the operator must stand directly behind the ~~unit~~ equipment to allow the shield to function as designed.

ITEM 5. Amend subparagraph **41.1(7)“h”(2)** as follows:

(2) The tube housing and the PID for stationary or mobile systems shall not be ~~hand-held~~ held by the operator during an exposure.

ITEM 6. Amend paragraph **41.1(7)“i”** as follows:

i. ~~Portable or hand-held~~ Handheld dental X-ray systems. ~~Portable or hand-held dental X-ray systems designed with a backscatter shield shall:~~ Only equipment specifically designed by the manufacturer to be held by the operator for intraoral dental X-ray exposures is allowed to be operated pursuant to this subrule.

- ~~(1) Be used only where it is impractical to use a portable dental system;~~
- ~~(2) Be used as the manufacturer indicates;~~
- ~~(3) Not be used with the backscatter shield removed, if applicable; and~~
- ~~(4) Be exempted from 41.1(4)“g.”~~

(1) Operators shall be specifically trained to operate the equipment. Records of training shall be kept at the facility until the operator is no longer an employee or until the equipment is removed from the facility.

(2) Protective aprons of not less than 0.25 millimeter lead equivalent shall be provided for operators to wear while operating the equipment.

(3) Dosimetry shall be provided for operators who are expected to exceed 10 percent of the annual occupational dose limit as outlined in 641—40.84(136C).

(4) Operators shall operate the equipment according to the manufacturer's instructions.

(5) The image receptor used must be digital radiography (DR), computed radiography (CR), or intraoral film with a speed class designated as "E/F" or a film with a faster speed designation than "F" or "E/F."

(6) No individual except the equipment operator may be within a radius of at least 6 feet from the patient during exposures.

(7) The equipment shall not be operated unless the backscatter shield is in place as designed by the manufacturer.

(8) The equipment shall not be operated in hallways, waiting rooms, or other areas where access for individuals of the general public cannot be controlled.

(9) The equipment shall be held without any motion during a patient examination. If the operator has difficulty in holding the equipment stationary, the operator shall use a tube stand. The equipment shall be operated on a tube stand whenever practicable to avoid unnecessary motion and retakes.

(10) When not in use, the equipment shall be stored in a manner that would prevent inadvertent exposures or use by unauthorized individuals.

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EDITOR'S NOTE: For replacement pages for IAC, see IAC Supplement 6/7/17.